Perfection and evaluation of patient specific guides for total knee arthroplasty : a cadaveric study : review of literature since 2006 = Mise au point et évaluation des guides de coupe patient spécifique pour la mise en place des prothèses de genou : étude cadavérique : revue de la littérature depuis 2006

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AVERTISSEMENT

LIENS

Université Joseph Fourier
Faculté de Médecine de Grenoble

Année : 2013 N°

PERFECTION AND EVALUATION OF PATIENT SPECIFIC GUIDES FOR TOTAL KNEE ARTHROPLASTY. A CADAVERIC STUDY.

Review of the literature since 2006.

(Mise au point et évaluation des guides de coupe patient-spécifique pour la mise en place des prothèses de genou. Etude cadavérique. Revue de la littérature depuis 2006.)

Thèse présentée pour l'obtention du doctorat en Médecine
Diplôme d'Etat

Thèse soutenue publiquement à la Faculté de Médecine de Grenoble
le 17 septembre 2013

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Remerciements

Cette thèse doit beaucoup aux nombreuses personnes qui m'ont encouragée, soutenue et confortée tout au long de cette année.

Je souhaite remercier Mr le Professeur Merloz pour avoir proposé et encadré cette thèse.
Je remercie les membres du jury pour avoir accepté de juger mon travail.
Mr le Professeur Saragaglia, vous m'avez donnée de bonnes bases en chirurgie prothétique, j'ai essayé de reproduire ce que vous m'avez enseignée lors de ce travail, en espérant avoir été à la hauteur.
Mr le Professeur Tonetti, vous nous tirez toujours vers le haut, vous nous poussez à donner le meilleur de nous même, j'espère que je serai à la hauteur.
Mr le Dr Chambat, merci d'avoir accepté de juger mon travail , c'est un réel honneur pour moi.

Mes parents, merci de m'avoir toujours soutenue et d'avoir cru en mes capacités, dans tout ce que j'ai entrepris, le ski, la médecine....
Mes grands parents, les mots seront toujours trop faibles pour vous exprimer ma gratitude, vous m'avez été d'une aide précieuse pour mes premières années de médecine, mais surtout vous m'avez beaucoup apportée sur le plan humain.
Ma Mamie, ma soeur et mon frère.

Jonathan, depuis plus d'un an tu es mon meilleur soutien, ton calme et ta sérénité ont été une aide précieuse. Merci d'avoir été là dans les moments difficiles.

Philippe et Nathalie du labo d'anat, merci pour votre aide, désolé pour les retards répétitifs. A Nicolas Demanget sans ton aide je ne serai jamais arrivée au « bout » de ce travail !!! et merci a toute l'équipe d orthotaxy de m'avoir fait confiance.

Pour tous les bons moments pendant mes études de médecine: Delphine, Klo, Dorlane, Camille, Elo, Christelle, Emma, et toutes celles et ceux que j'oublie.

Aux personnes qui m'ont tant appris pendant mon internat : dans l'ordre chronologique :

- les Drs Chirpaz et Jager, ceux qui essuient nos erreurs de jeunes internes (les sections de long plamaire ne sont pas à suturer !!);
- le Dr Skowron de la rigueur et du sérieux, oui mais il faut savoir aussi détendre l'atmosphère (qu'est ce que vous m'avez fait souffrir sur ma première appendoc' !!!! mais qu'est ce que je me suis marrée sur vos imitations (« I am burning in the sky.... »));
- aux chirurgiens de l'hôpital Sud : Numa : l'arthro d'épaule c'est le kiffe (enfin plus à voir qu'à faire !!); Mathieu : merci pour ta pédagogie, ta gentillesse... j'aurai aimé faire plus de bloc avec toi; Marc : oui je voulais opérer mais je ne savais pas la technique, mais tu m'as quand même un peu laisser faire !!!; Gilles, Christophe et Brice,

- aux chirurgiens de Chambéry : Dr Monbarbon, merci de m'avoir laisser faire des PTG, ce fut une grande aide pour ce travail, Dr Beaudouin : merci d'avoir améliorer mes connaissances en chirurgie du membre supérieur.
- à l'équipe de la main : j'ai passé un excellent semestre avec vous, Pr Moutet : votre langage chirurgical était pour moi au début du chinois, maintenant je sais ce qu'est un Ishiguro (enfin lui il est japonais !), Dr Corcella : je veux bien perpétuer les échanges génépi- sanglier !, Dr Forli : Madame oui oui versus Madame Pourquoi, merci d'avoir pris le temps de répondre à mes innombrables questions. Marie que de bons moments au bloc et en dehors!!!
- aux chirurgiens de Nord : Dr Milaire, Nicolas M., Steve, Nicolas M-S.
- Pr Mansat, merci pour votre gentillesse, merci de m'avoir accueillie dans votre service, de combler mes (grosses) lacunes en chirurgie du coude et l'épaule, et désolé mais je ne sais pas si un jour les SNAC et les SLAC feront partie de mon domaine de compétence.

Et enfin et mais pas des moindre tous mes co internes qui ont fait que mes 5 ans d'internat restent un très bon souvenir, chacun de vous m'a apporté un petit quelque chose sur le plan professionnel et quelques fois personnel.
- Honneur aux filles, Lydie et Charline, nous n'avons pas été souvent co internes que ce soit avec l'une ou avec l'autre, jamais toutes les 3 (peut être que ce n'est pas plus mal !!!!!), merci pour votre soutien, votre bonne humeur, ne changez rien !!!!
- les Sudistes : Bouchette, Grasset, et futur Sudiste Roch
- les Nordistes: Gaël et Seb, je pense que mes remerciements seront surtout en 2015 si je survis à mon assistanat à Nord!!!
- les plus jeunes: Boud', Marques Da silva de la caravane, Jean Nad, Rouchy, Roudet, Belvisi, petit Billy (je compte sur toi pour l'arthro d'épaule), Cognault, Rabattu (la chir ped un enfer!!), Sage (tu ne seras pas orthopédiste mais tu sais faire les ongles incarnés!!!)
- les toulousaines: Steph, Dr the good, Florie, merci pour votre accueuil (quand vous voulez pour un resto entre filles!!)

et les autres croisés pendant de stage en périph : David (ami fidèle, merci pour le coup de main sur la mise en page !), Chateau (je t'attend pour quelques descentes en télémark !)

Les équipes des services d'orthopie 13ème, du bloc ortho Nord et bloc PU, j'espère que je serai à la hauteur à partir de novembre !!! enfin préparer bas de contention, boules quies et patience !!

En espérant n'avoir oublié personne !!!!

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TABLE of ABBREVIATIONS

TKA	Total Knee Arthroplasty
PSG	Patient Specific Guide
SI	Standard Instrumentation
CAS	Computer Assisted Surgery
HKA	Hip-Knee-Ankle
MFA	Mechanical Femoral Angle
MTA	Mechanical Tibial Angle
CT Scan	Computed Tomography Scan
MRI	Magnetic Resonance Imaging
HKS	Hip-Knee-Summit angle

ABSTRACT

Introduction: Coronal alignment in total knee arthroplasty (TKA), regarding the literature, seems to be a major factor in the survivorship of the components and in the functional outcome. The Patient Specific Guides (PSG), based on 3 D imaging, had been introduced in surgical process in order to improve accuracy in TKA, and to reach post operative neutral mechanical alignment.

Hypothesis: Compared with standard instrumentation (SI), PSG can improve the coronal alignment of the TKA and decrease the operative time.

Materials and methods: Thirty-three lower limbs (from femoral head to foot) have been taken from seventeen cadavers. A pre operative CT scan of each lower limb has been realized in order to measure: HKA angle, MFA and MTA, and to plan the TKA for shaping the PSG.
17 TKAs have been implanted with PSG, 16 with SI. 54% (18/33) knees presented osteoarthritis at least on one of the three compartments. Post operatively, a further CT scan has been used to make the measures to compare the two groups. Per operatively, operative time and positioning of PSG have been reported.

Results: Pre operatively, 66,7% (22/33) of the lower limbs were in varus, 27,3% (9/33) were in valgus and 6% (2/33) were in neutral alignment, there was no significant difference between the groups. Post operatively, the overall mechanical alignment was between 177° and 183° for 81,25% (13/16) in SI group, and 76,47% (13/17) in PSG group. The mean HKA in SI was 179,1° (±2,45), and 178° (±2,18) in PSG group, there was no significant difference between the group (p-Value: 0,17). Only the operative time was significantly lower in PSG group with a median of 43 minutes [35-47] relative to the SI group with a median of 50 minutes [43-62,5] (p-Value: 0,041).

Conclusion: in our study, PSG did not demonstrate a superiority regarding the coronal mechanical alignment comparing with SI in TKA. But the use of PSG process can reduce the operative time.

INTRODUCTION

Over the last decade, the incidence of total knee arthroplasty (TKA) increases of 60%, and for the next ten years the forecast increase exceed 100%(1). The success of TKA depends on multiple factors whose limb alignment, component positioning and soft-tissue balancing(2). Accurate coronal alignment is correlated with good clinical outcomes(3)(4) and contribute to implant longevity(5)(6)(7).

To improve component alignment, computer assisted surgery (CAS) have been introduced, and have demonstrated to be of great value in improving the longitudinal alignment of the limb compared to results with traditional alignment techniques(8).

Recently, a meta-analysis showed that malalignment of the mechanical axis of more than 3° occurs in 30% with standard instrumentation, for only 10% with computer-assisted TKAs(9).

But these systems have some per operatively drawbacks such as accurate landmark registration, increased surgical time and cost, bone fractures, complexity, long set-up time and substantial learning curve(10)(11).Moreover, it has not completely eliminated component outliers (8)(12)(13)(14).

Nowadays, in alternative of computer navigation and conventional instrumentation, emerge patient-specific guide (PSG) based on three-dimensional imaging, to improve postoperative alignment and implant positioning.
These patient-specific guides are designed from 3-D imaging of precise anatomic knee of one patient. They are precisely drawn to match specific landmarks of each patient's knees.
Proprietary software is used to virtually map bone resections and to accurately size and position the knee implant.(10)

The use of PSG should improve the accuracy of bone cuts, but papers published until now are contradictory, some authors found an improvement in coronal alignment using PSG(15)(16), others did not(17).

The aim of this study is to compare TKA implanted with standard instrumentation (SI) versus PSG from computerized tomography scan model, regarding limb alignment, per operative accuracy PSG fitting and operative time, on 33 cadaveric lower limbs; and to compare our results with a review of the literature.

MATERIELS AND METHODS

ANATOMICAL PIECES:

Thirty-three cadaveric lower limbs were obtained from the Anatomy Laboratory at Joseph Fourier University. On 16 cadavers the 2 lower limbs have been chosen. For one cadaver only one lower limb was available. The anatomical pieces were divided in two groups: PSG group (17) and SI group (16).

PREOPERATIVE COMPUTERIZED PLANNING

First, a spiral 3D CT scan (Radiology Departement of Grenoble university hospital) was performed on every lower limb with a 0,5mm slice thickness from the femoral head to the ankle.
The images were stored in DICOM format and transferred to workstation running the planning software to determine hip, knee and ankle centres.

The femoral head was considered as a sphere, and its centre could then be identified. The middle of the tibial spine was chosen as the knee centre. The ankle centre was the midpoint of the bimalleolar axis. Figure 1.
For each knee: HKA (Hip knee ankle angle), MFA (mechanical femoral angle) and MTA (mechanical tibial angle) were measured.

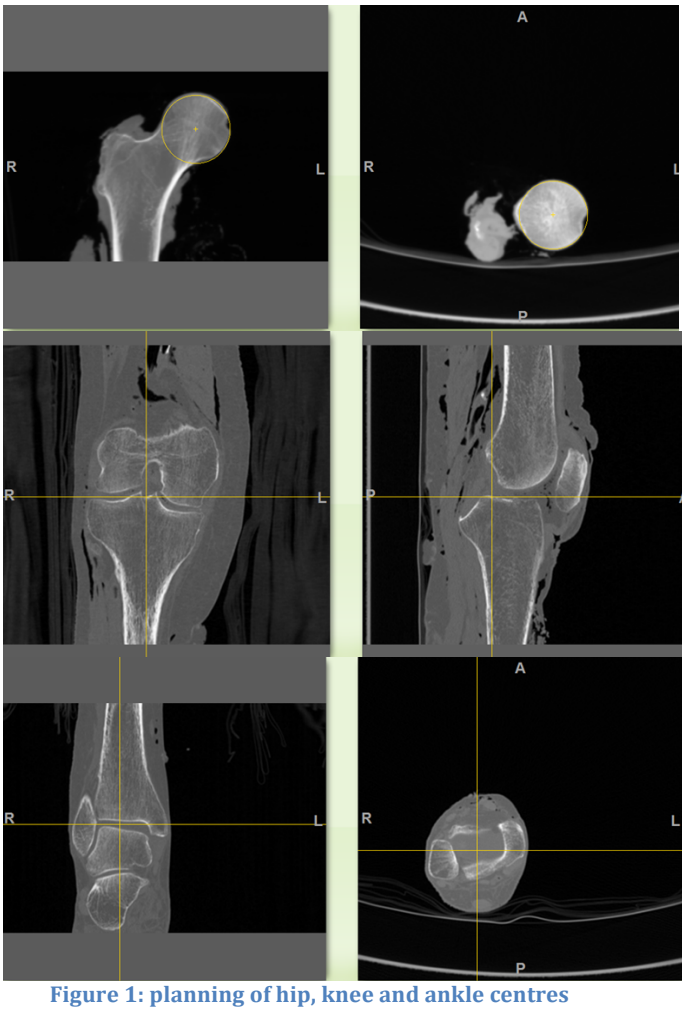

Figure 1: planning of hip, knee and ankle centres

HKA angle is the line from femoral head centre, passing through the knee center, to the ankle centre.

MFA is the angle comprised medially between mechanical femoral axis (line from centre of femoral head to knee centre) and the bicondylien line (or the distal tangent of the femoral component)

MTA is the medial angle between mechanical tibial axis (line from knee centre to ankle centre) and the tangent of the tibial plateau (or tibial component).

Pre operatively: 66,7% (22/33) knees had genu varum, 27,3% (9/33) knees had genu valgum and 6% (2/33) were in neutral position.

With the planning software, for the knees in PSG group, the total knee arthroplasty (TKA) was planned preoperatively. Optimal alignment (HKA equal to 180°) and osteotomy positions (the thickness was depending of type of HKA) were identified. Each tibial PSG was constructed with a 10-mm resection height. Each femoral PSG was also constructed with a 10-mm resection height and two drill guides to define the rotational alignment of the femur. The posterior slope of the tibial PSG was 2°, and the flexion of femoral PSG was 5°, as recommanded by Evolutis™. Figure 2.

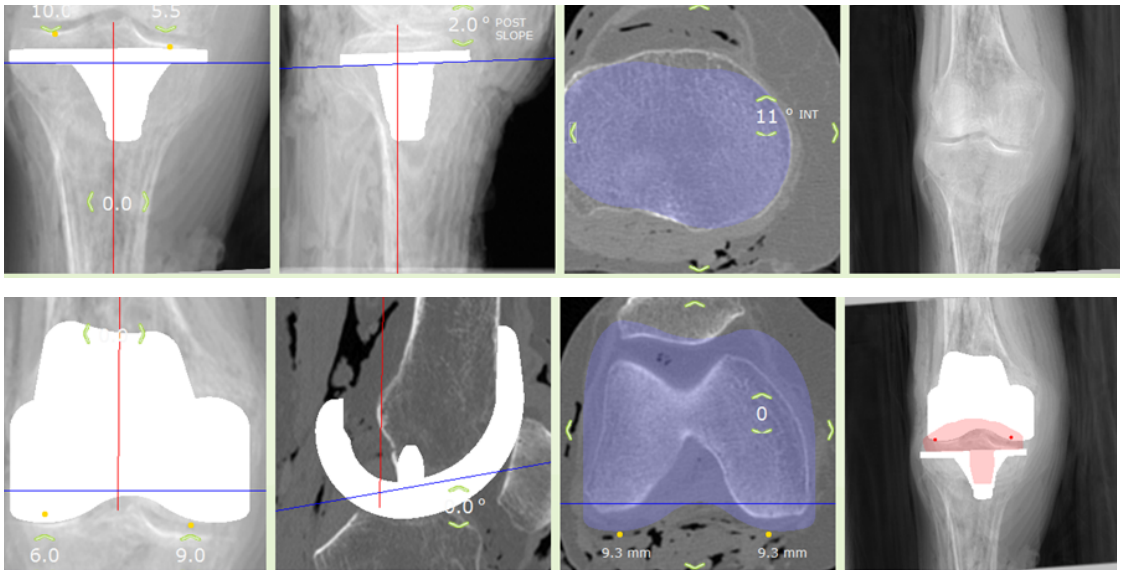

Figure 2 : Pre operative planned TKA with PSGs

The contact areas of each PSG were created to precisely match bone surfaces related to the patient's anatomy. Figure 3.

- For the tibial PSG: the pre spinal surface, the anterior medial epiphyseal and the anterior edge of the lateral tibial plateau. (et médial)
- For the femoral PSG: the anterior cortex of the metaphyseal, the medial edge of the medial distal condyle and the lateral edge of the lateral distal condyle.

The stability of each PSG was inspected before surgery. Moreover, PSGs were positioned on their corresponding bone models to confirm their perfect fit.

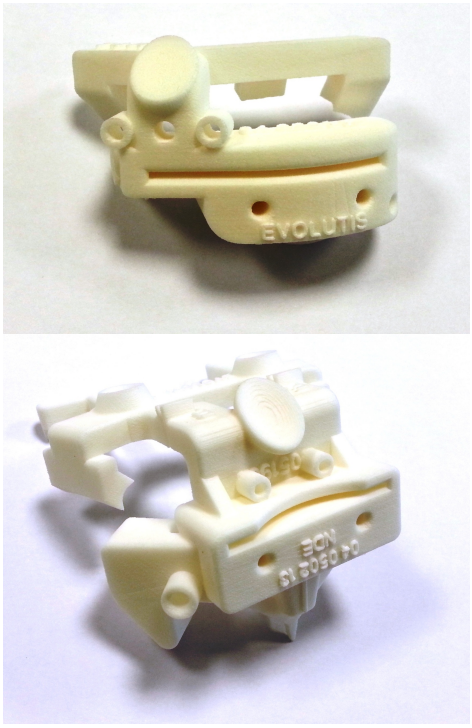

Figure 3: femoral and tibial PSGs

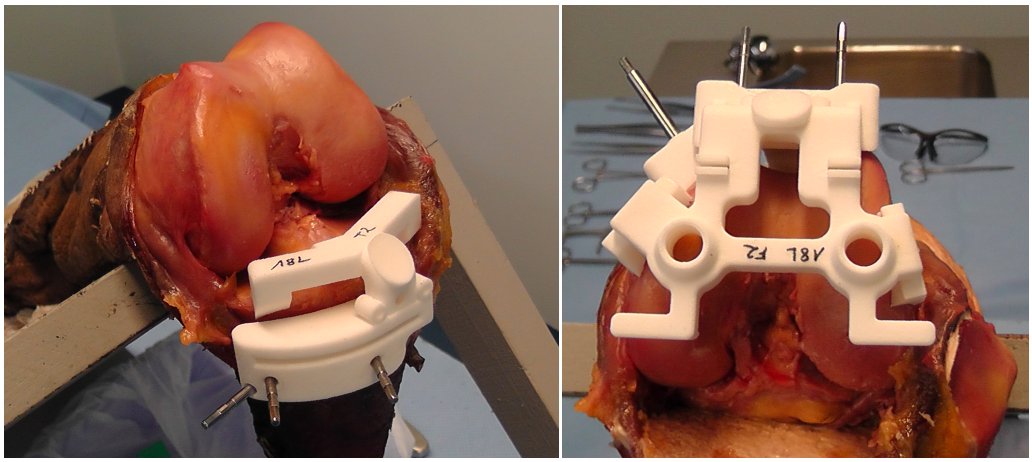

Figure 4: PSGs placed on corresponding landmarks

The femoral and tibial bone models, and their corresponding PSGs were made of nylon (polyamide). Figure 4.

OPERATIVE PROCEDURE

All operations were performed by the same surgeon (S.D.L.).

After medial arthrotomy, and lateral eversion of the patella, the tibial PSG was placed and the proximal tibia cut was made through PSG cutting slot with a blade mounted on an oscillating saw.
Then the femoral PSG was placed from the anterior part of the distal femoral bone to the distal medial and lateral part of the condyles.
Two K-wires were used to mark the position of the rotational alignment depending on ligament balancing in flexion.

For the standard process, an intramedullary system was used for the placement of the femoral (aided with the HKS (hip knee summit angle)) and tibial osteotomies.

The surgical technique is detailed in annex 1.

Trial components present in the Evolutis™ Rolflex plateau were used to replace the knee joint.

POST OPERATIVE PROCEDURE

Each lower limb received post operatively a CT scan with the same procedure as pre operatively, to measure HKA, MTA and MFA. The same independent observer made the measures.

EVALUATION CRITERIA

For each knee, some criteria have been measured and reported.

Pre-operatively:

- On CT scan images: HKA, MFA, MTA, and the size planned for PSG group.

Per operatively:

For every lower limb:

- Osteoarthritis of each compartment: patella, trochlea, femoro-tibial compartment, medially and laterally.
- Plumb line alignment (cord pulled from femoral head centre to the ankle centre) referred to the internal edge of the anterior tibial tubercle, and to the knee centre (middle of tibial spines or middle of tibial component) after the lateral everting of the patella and before closing the skin.
- Operating time: The operator must measure the duration of the surgery (skin-to-skin time).
- Ligament balancing: at the end of the surgery, the operator checked the ligament balancing in flexion and extension.

For PSG group:

- Good positioning of the PSG: The operator had to evaluate if the PSG was well positioned before performing drills and cuts. The PSG was considered well positioned if all degrees of freedom of the PSG were blocked when the operator presses strongly on the finger mark present on the PSG.

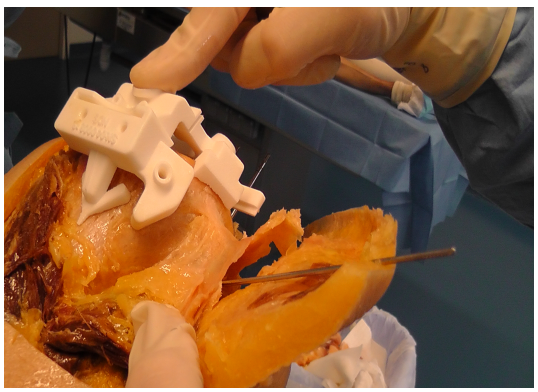

Figure 5: test of PSG stability

- Recut: It had to be indicated if the operator had to perform a recut after the first cut performed with the PSG. The height of the recut was also reported.

- Revert to conventional surgery: The operator had to report if he had to use conventional instrumentation instead of PSG to perform TKA if he came across a problem during the procedure.

Post operatively:

- On CT scan images: HKA angle, MFA, MTA.

ANALYSIS of the LITERATURE

The research of articles was made on pub med, selecting the study employing PSG in TKA. Case reports, and articles studying PSG and patient specific arthroplasty in the same procedure were excluded. In each article, number of TKA, type of PSG, type of 3 D images, coronal alignment, percentage of outliers and operating time were reported when they were studied.

STATISTICAL ANALYSIS

The normality of quantitative parameters was tested by Shapiro Wilk test and variances' homogeneity with Levene test.

Groups' comparisons have been realized by the Student t-test when the sample was normally distributed or by the Mann-Whitney-Wilcoxon test otherwise.

For the comparison pre and post operatively in the same group, the same test has been involved but on paired data.

Concerning the operative time comparison, the ANOVA has been used tacking into account two factors (group and help). A data log transformation was carrying out to confirm the data homoscedasticity for multivariate analysis. The correlation between two parameters was assessed using the Spearman correlation coefficient.

Learning curves were plotted to see if there has been an improvement over time for the post-operative HKA angle and time of surgery.

All P-values were two sided, with a P-value less than 0.05 was considered to indicate a statistically significant difference.

Analysis was performed in July 2013 by using GNU R software (2.15.0) (Vienna, Austria).

RESULTS

Wording:

When the normality of the parameter distribution was obtained, the results were described by their means and standards deviation. Otherwise it was described by its median, 25% and 75% percentiles.

Comparison pre and post operatively in the groups:

SI group:

	Pre op.	Post op.	p-Value
HKA	178 [177,8;181]	180 [177;180,2]	0,47
MFA	93 (2.13)	92 (1.21)	0,13
MTA	88 [86;89]	88 [87;89]	0,36

Table 1: Pre and post operative alignment in SI group

There were no statistical differences in this group between the measures made pre operatively and those made post operatively. Table 1.

PSG group:

	Pre op.	Post op.	p-Value [CI]
HKA	178 [178;180]	178 [177;179]	0,90
MFA	92 [92;93]	92 [90;93]	0,24
MTA	88 [86;88]	89 [88;89]	0,02

Table 2: Pre and post operative alignment in PSG group

For the HKA and MFA there were no statistical differences between the measures made pre operatively and those made post operatively. Concerning the MTA there was a statistical difference between the pre operative and the post-operative measures. The estimation of this difference is 1.5 [0.5;2.5]. Table 2.

Comparison between the groups:

Pre operatively:

Regarding the HKA angle: 66,7% (22/33) of the lower limbs were in varus (<180°), 27,3% (9/33) were in valgus (>180°), and 6% (2/33) were in neutral position.
There was no statistical difference between the two groups concerning the HKA, MFA and MTA angles. Table 3.

	SI	PSG	p-Value [CI]
HKA	178 [177,8 ;181]	178 [178 ;180]	0,64
MFA	93 (2.13)	92,35 (1.32)	0,3
MTA	88 [86 ;89]	88 [86 ;88]	0,65

Table 3: Comparison of pre operative alignment between the groups

Per operatively:

54% (18/33) of the knees had osteoarthritis on one or more of the three compartments.

For the PSG group, the reverse to standard instrumentation hadn't been necessary.

For the positioning of PSG, four times the PSG had been difficult to place, once on the tibial plateau, and three times on the femoral landmarks.

Regarding the necessity of recut in PSG group, 11,8% had been necessary, corresponding of 2 knees, with a recut of the tibial plateau of 2 mm.

Concerning the PSG group, the sizes of the components between the planned TKA and the effective TKA, 5 femoral components were planned one size smaller than the effective size used for the TKA.

For the PSG group, the polyethylene (PE) size was 8 mm for 12/17 TKA, for the five other ones the size was 10 mm. For the SI group, 10/16 PE were 8 mm, 3/16 were 10 mm and 3/16 were 12 mm.

Post operatively:

78,8% (26/33) of the lower limbs were axed between 177° and 183°, representing 76,47% (13/17) in PSG group and 81,25% (13/16) in SI group. 23,5% in PSG and18,75% in SI group were considered as outliers (out of the window 180°+/-3°), all of this outliers were in varus (< 177°).

There was no statistical difference between the two groups regarding the HKA, MFA and MTA angles.

	SI	PSG	p-Value [CI]
HKA	179.1 (2.45)	178 (2.18)	0,17
FMA	92 [91 ;93]	92 [90 ;93]	0,72
TMA	88 [87 ;89]	89 [88 ;89]	0,11

Table 4: Comparison of post operative alignment between the groups

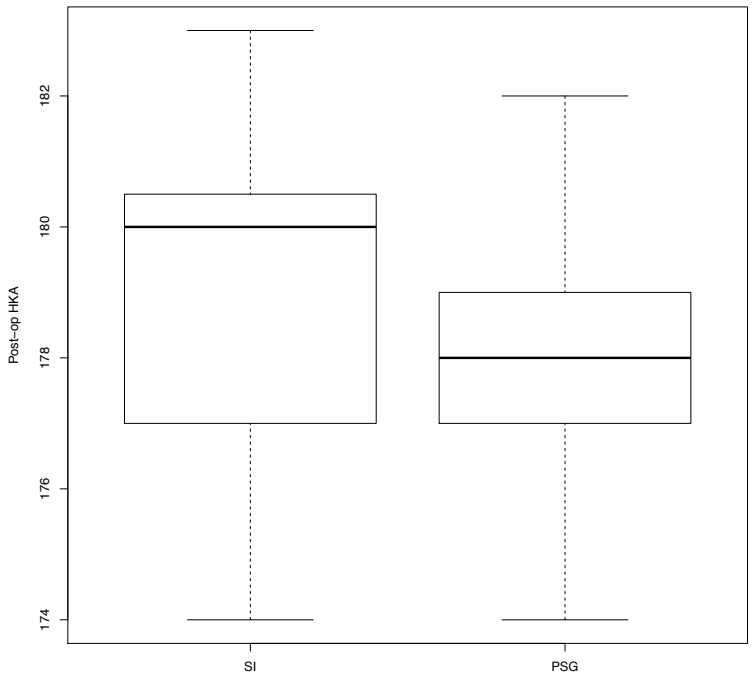

Figure 6: Boxplot post operative HKA

In order to have a statistical difference between the two groups, with a power of 80%,the sample must have 75 lower limbs in each group.

Plumb line:

Pre operatively and post operatively, the measures made with the plumb line compared with the knee centre and the internal edge of the anterior tibial tubercle are correlated together but there is no correlation between these measures and the HKA angles.

Operative time:

The median time for SI group was 50 minutes [43; 62,5], this time was 43 minutes [35 ;47] for the PSG group. There was a statistical difference with a p-value at 0,04.
When the surgery was achieved with help, the median time was significantly lower for the PSG group than the SI group (p-value= 0,02), but there was no difference of operative time between the two groups when the surgery was realized without help (p-value= 0,69). Table 5.

Help	Method	Min	Q1	Median	Mean	Q3	Max	SD	N	P.value
With help	SI	50	50	53	54	57	60	4.9	4	0.017
	PSG	30	34	42	39.89	44	55	8.07	9	
Without help	SI	38	42.25	44.5	60.17	71.25	140	30.25	12	0.699
	PSG	32	42.75	45.5	47.88	52.5	65	10.49	8	

Table 5: Operative time by group and help

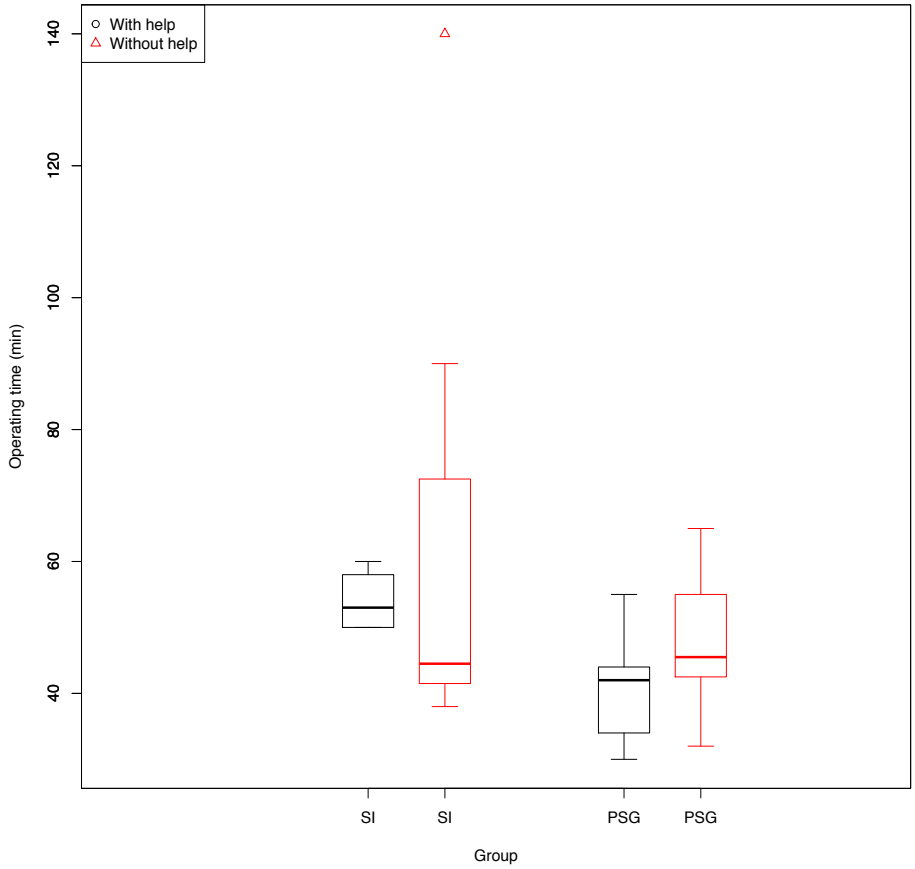

Figure 7: Boxplot operative time by group

The median operative time for the group with help is 44 minutes [35; 50], for the group without help is 44,5 minutes [42,75; 61,25].

There is no statistical difference between the operative time with help and the operative time without help (p-Value =0,25). Figure 7.

So, according to the ANOVA's results, only the group has an influence on the time (p-Value of the group factor = 0.02 and p-Value of the help factor = 0.3). Table 6.

	Df	Sum Sq	Mean Sq	F value	Pr (>F)
Data PSG	1	0.5184	0.5184	6.018	0.0202
Data Help	1	0.0950	0.0950	1.102	0.3022
Residuals	30	2.5845	0.0861		

Table 6: ANOVA study results

Learning curve:

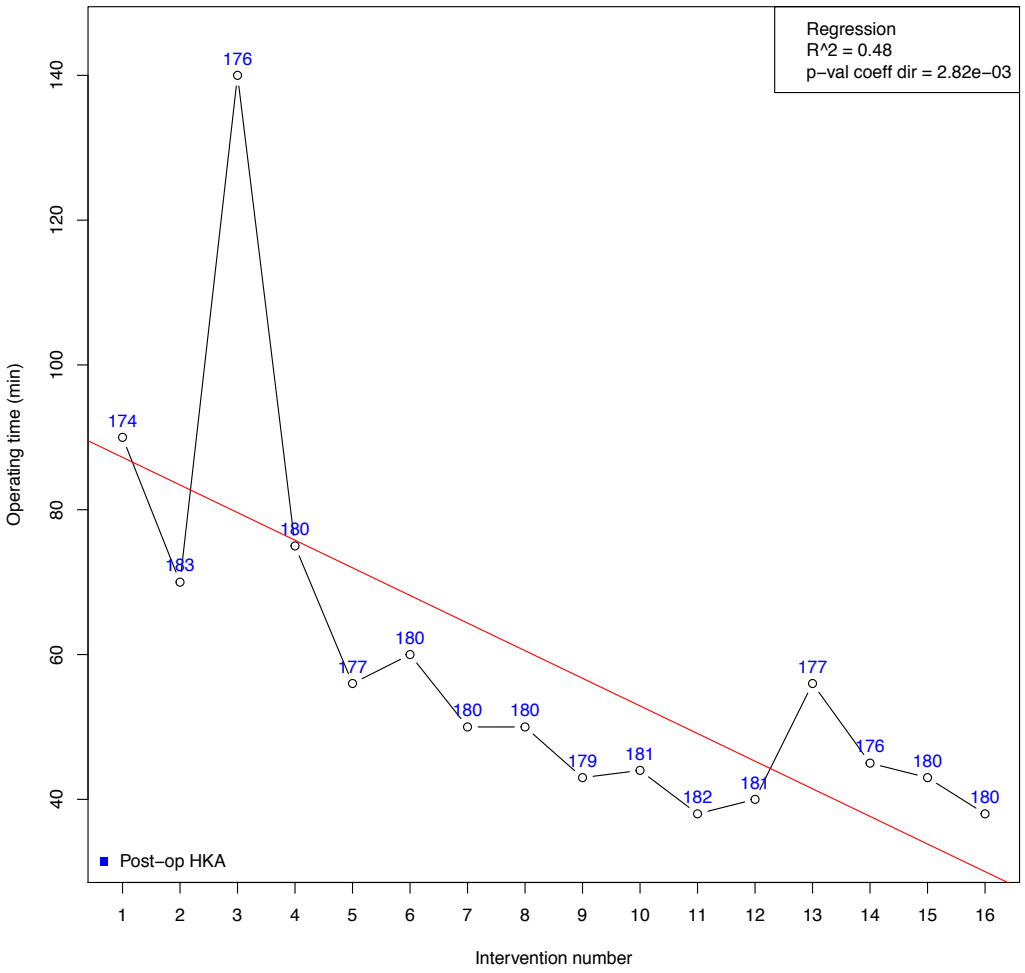

Figure 8: learning curve operative time SI group, with HKA of each knee

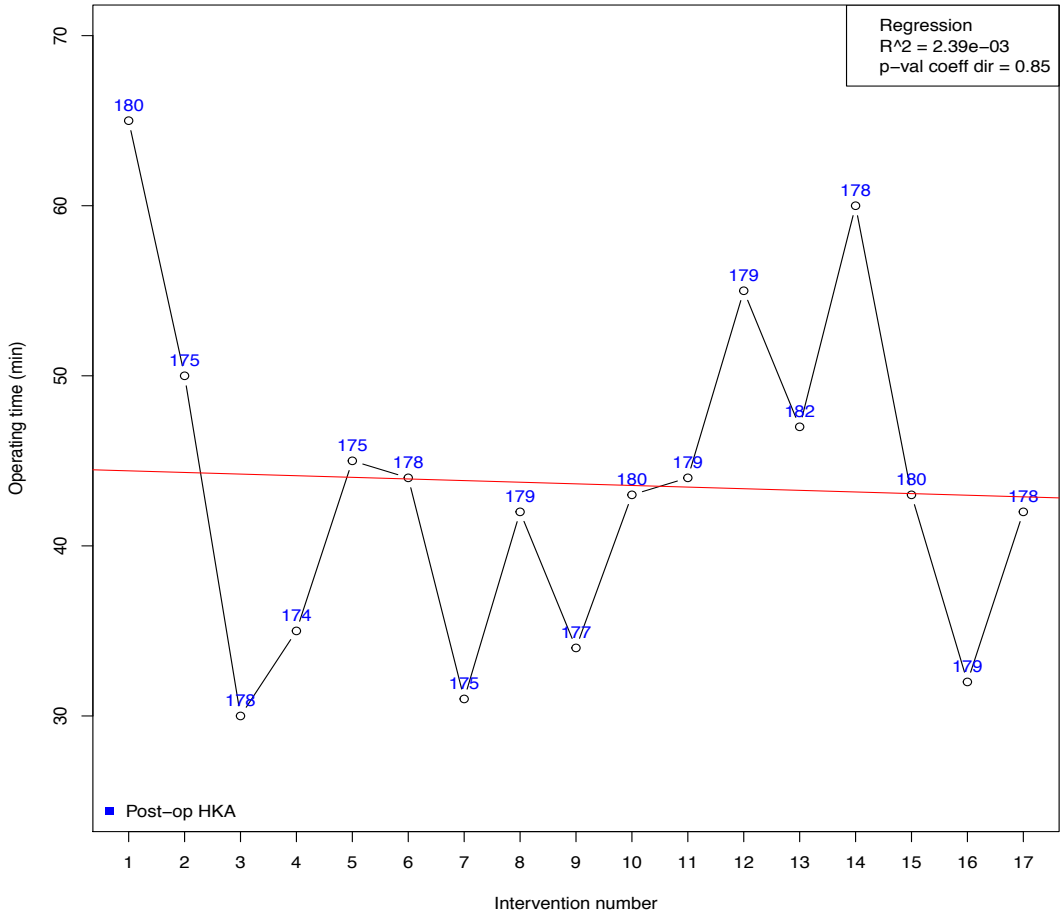

Figure 9: learning curve operative time PSG group, with HKA of each knee

Review of literature:

The tables summering the articles are presented in annex 2.

DISCUSSION

Review

Regarding the literature, the percentage of outliers is comprised from 0% to 75%.
Concerning overall mechanical alignment, in the comparative studies, if we take into account each PSG group in multiple comparative group as one independent group, 6 comparative studies over 12 found more outliers in PSG group than the SI or CAS groups.
The papers which studie PSG produced in order to reach neutral overall mechanical alignment (such as Signature, visionnaire, Tru Match): the percentage of outliers run from 9,40% to 45%.
When the PSG was a Otis Med (which kinematically align the lower limb), the percentage is comprised between 9,52% and 75%.

Concerning the operative time, all the papers comparing this criteria with SI group found a lower operative time in PSG group than SI group.

Alignment

We investigated this alleged improvement in 3D, using postoperative imaging as measurement tool and standard instrumentation as a control cohort.
In our controlled cadaveric study, the use of PSGs did not improve the mechanical alignment of TKA.

Since few years, in the literature many articles studied the accuracy of PSG in TKA, but most of them are not comparative studies.

For validating the usefulness of PSG, the goal is to establish its equivalence or superiority to existing modalities: standard instrumentation and Computer Assisted Surgery (CAS).

In our study, pre operatively, there was no statistical difference between the two groups regarding the three angles (HKA, MFA and MTA).

Post operatively, the mean HKA in PSG group was 178° +/-2,18° versus 179,1° +/- 2,45° in SI group and there was no statistical difference between the groups. Concerning the HKA outliers (outside of 180° +/- 3°), there were more outliers in PSG group (23,5%) than in SI group (18,75%).
Regarding the MFA, the median angle in PSG group was 92° [90; 93] versus 92° [91; 93] in SI group, the percentage of outliers over 90° +/- 2° was: 35,3% in PSG group and 31,25% in SI group.
Concerning the MTA, the mean angle was 89° [88; 89] in PSG group and 88° [87; 89] in SI group, the percentage of outliers over 90° +/- 2° was lower in PSG group with 17,65% than SI group with 31,25%.

Regarding the comparative studies in the literature, Ng and al.(16), described a similar mean HKA angle between the groups (PSG: 180,6°, SI: 181,1°), but found statistically less HKA outliers in PSG group (9%) than in SI group (22%).

Noble et al.(15) also found a statistically mechanical alignment closer to neutral zero with the PSG.

In an other hand, Nunley et al.(18) compared 3 groups: 1 group SI, 1 group PSG aligned on mechanical axis and 1 group PSG aligned on kinematic axis, they found 16% outliers in HKA angle in the SI group versus 18% in the PSG subgroup that targeted neutral mechanical alignment and 44% in the PSG subgroup that targeted kinematic alignment. They concluded that PSGs did not improve coronal alignment.

This studies used as PSG, three kinds of different trademark, we can ask if the difference in improvement or not, is due to one kind of PSG.

In a prospective randomized controlled trial, Victor et al.(19), compared four kinds of PSG systems analyzed by both CAS and 3-D radiographic and concluded that these systems did not improve the accuracy of TKA, the PSG procedure was modified in 28% of PSG group (inappropriate size component and level of cut).
And this system did not reduce the number of outliers in any plane in space. The CAS permitted to eliminate the per operative outliers more than 3° in any plane (coronal and

sagittal), but the statistical analyses included the original incorrect value, the PSG procedure had to be abandoned in more than one of five patients.

Some authors compared PSG versus standard instrumentation, regarding the mechanical axis in coronal alignment of the lower limb; three of them(20)(21)(22) did not find any statistical difference between the groups, but two of them(20)(22) found a statistical difference concerning the back slope of the tibial component in sagittal plane.

In our study, as regard the accuracy, the need of recut or changing size of the component during surgery, occurred two times for the recut and 5 times (over 17) for the changing size component, exclusively on femoral component. There were non-overhang tibial component.
In comparative study, Stronach et al. (23) indicated that Patient-specific instrumentation predicted the implanted component size in only 23% of femurs and 47% of tibias over 66 TKA. They also pointed the lack of accuracy of these PSGs concerning the alignment of TKA. They analyze the number of directed changes made by the surgeon in order to improve the positioning of TKA implanted with PSG. 2,4 changes per knee occurred, regarding the radiographically measureable changes, 21/95 involved alignment, and 17/21 of the changes were an improvement. The principal drawback of this study is the fact that all changes are subjective.

In most of the comparative studies (15)(16)(18)(20)(21)(22)(23)(24)(25) unlike to our study, the PSG guides were planned from MRI images.
Or one study compared the accuracy of MRI versus CT imaging in patient specific templates for total knee replacement surgery(26), and concluded that the model generated from the CT data were superior to those generated from the MRI, with less numerous discontinuities and unwanted artifacts on the external surfaces.

Only one article(19) studied four subgroups of PSGs images based on either CT scan or MRI, and compared the 4 subgroups together and also to a SI group, they found no statistical difference in the limb alignment in the three planes (coronal, sagittal and rotational).

Ng et al.(16) who demonstrated a lower percentage of otuliers in PSG group, also compared their results of TKA with PSG, with a review of literature concerning CAS, they found a number of outliers comparable to CAS.

Operative time

Concerning the operative time, our study showed a statistical reduced time surgery in PSG group, with a median time in SI group of 50 minutes, versus 43 minutes for PSG group. This finding was also supported by previous study.(15)(22)(24)(21). Stronach et al.(23) did not find a reduction of time surgery mainly cause of the surgeon directed changes per operatively. This operative time did not take into account, the time needed for preoperative planning and confirming the final plan.

Others findings

Concerning the plumb line measures, those were not correlated with the HKA angle, but were correlated together. This lack of correlation with the HKA angle is may be due to the medial to lateral size of each knee. This explanation can also highlight the fact that there is a correlation between the plumb line measures themselves.

Learning curve: the graph representing the learning shows a decrease of the operating time greater in the SI group than in PSG group, without so much differences in HKA angle.

Cost effectiveness:

In our study, the price for the production of a pair of PSG (tibial and femoral cutting blocks) was assessed to 500€ without taking account of the realization of CT scan.

Tibesku et al.(27) compared the economic impact of PSG with SI in TKA, based on activity-based costing (ABC). The parameters of the ABC model were: implants and cutting, personnel costs, diagnostics, hospital costs. The operating time saving observed in our study and others(15)(24)(21), the use of less trails during surgery led to save money. The analysis

was established on 350 TKAs per year. Tibesku et al. concluded if the saved time was utilized to perform procedure other than TKA (total hip arthroplasty, arthroscopy...), this will result in additional revenue of 78 240€ per year to the hospital.

Hafez et al.(28) demonstrated that PSG is cheaper than SI TKA. The explanation is the following: the cost of a set for SI process is 30 000$ every 5 years, based on 150 TKAs every 5 years, the set of implant costs 200$ per TKA without the sterilization of the set (180$). The cost of the PSG in their study is 200$ per pair, and the CT scan: 100$ per specimen.

Limitations

This study had some limitations.
Firstly, this study was too underpowered (small patient population) to detect a statistical significance, concerning alignment. To have a statistical significance, with a power of 80%, the sample must have 75 lower limbs in each group.

Secondly, the cadaveric lower limb in this study did not have any severe pre-operative deformities (HKA range from 182° valgus to 171° varus).

Thirdly, the results are limited to the coronal plane and do not take into account component positioning on the lateral view. In addition, we could not assess for rotational alignment, the internal, external or neutral position was decided depending on ligament balance in flexion. Moreover the cadaveric knees were most of time rigid, so the testing of ligament balance in flexion and in extension should have been prevaricated.

Fourthly, the influence of the learning curve, the surgeon had no prior experience with PSGs, and the use of a new implant system is a potential bias. In the other hand, this surgeon had not so much experience in standard instrumentation.

Lately, the CT images had been controlled pre and post operatively by only one person, member of the society working out the PSGs.

Futures directions

Patient-specific instrumentation can be engineered to restore the knee alignment to either the mechanical axis or the kinematic alignment.

The kinematic motion of the knee can be referenced to the flexion-extension axis of the distal femur. This axis passes through the centre of the posterior femoral condyles consider as cylindrical.(29)(30)

To create the PSG, the arthritic knee model needs to be transformed in normal knee model by filling articular defects and removing osteophytes.

A recent study(31) on modern TKA showed that the 25% of patients who were outliers (3° varus or valgus) had better survivorship at 15 years than the 75% aligned within the 3° window. Moreover an another recent multicenter study(32) demonstrated that the malalignment of TKA out of HKA 180° +/- 3° was not a risk factor of failure.

Some authors performed TKA with PSG in order to reach this kinematic alignment corresponding to pre arthritic joint line.

Klatt et al.(17) in his study, report a high potential of malalignment of TKA component, but this article is based on only 4 TKA performed with PSG in order to reach kinematic alignment of the knee. The 4 TKA were performed under control of CAS, per operatively the overall alignment measured by CAS (referred to mechanical alignment) was between 5° valgus to 7,5° varus. The post operative X ray show a tibial component malalignment from 3° of valgus to 7° of varus, but no long leg X Ray were realized and the overall alignment was not evaluated.

Few months later, Howell et al.(33) reported, an initial experience with kinematic based PSG in 48 TKA. All TKA alignment were within +/- 3° of the neutral mechanical alignment. They also reported a high level of patient satisfaction and an acceptable clinical outcome at 3 months.

Spencer et al.(34), compared 21 TKA performed with PSG aligned on the kinematic trans cylindrical axis with previous studies 30 TKA performed with standard instrumentation. There were no statistical difference concerning coronal alignment based on mechanical axis compared with two previous studies based on standard instrumentation and CAS, with only two patients outlying 180° +/- 3°. Regarding to clinical outcome at 3 months and 6 months, PSG group flexion was greater than SI group, without statistical difference.

Dossett et al.(35), compared in randomized trial, 41 TKA based on kinematic axis using PSG with 41 TKA based on mechanical axis based on standard instrumentation. Knee and limb alignment were similar between the groups. And the functional outcome at 6 months was higher in the kinematically aligned group.

Recently Howell et al.(36), studied the outcome at minimum of 31 months with Oxford Knee Score and WOMAC scores among 214 TKA performed with kinematic based PSG, and allocated in three alignment categories for tibial component, knee and limb. The categories were classified in in range or outlier. There was no statistical difference between the groups regarding the functional outcome.

Other directions can be taken by PSG, in high deformity of femoral bone in which intra medullary rod cannot be used, or in case of osteopetrosis such as described by Mayer et al.(37), or for unicompartmental to TKA revision surgery described by Kerens et al.(38).

CONCLUSION

In our cadaveric study, patient specific guides (PSG) for total knee arthroplasty did not improve the coronal mechanical alignment of the lower limb compared with standard instrumentation procedure. Indeed, we obtained post operatively a mean HKA angle of 179,1°+/- 2,45° and 178°+/- 2,18°, and a percentage of outliers from 180° +/- 3° at 18,75% and 23,5%, in standard instrumentation and PSG groups respectively.

On the contrary, the operative time was significantly reduce in PSG group compared to standard instrumentation group. This result is corroborated by many authors. Some of them add that this diminution can lead to a reduction of cost effectiveness, despite of the price of this new technology.

The emergence of this technique, raise to a new concept of alignment of total knee arthroplasty, focused on kinematic alignment of the lower limb.

But further study is necessary to compare custom cutting guides with traditional instruments and computer navigation with regards to long term implant survival and functional outcome, regardless the type of lower limb alignment.

Introduction: Coronal alignment in total knee arthroplasty (TKA), regarding the literature, seems to be a major factor in the survivorship of the component and in the functional outcome. The Patient Specific Guides (PSG), based on 3 D imaging, had been introduced in surgical process in order to improve accuracy in TKA, and to reach post operative neutral mechanical alignment.

Hypothesis: Compared with standard instrumentation (SI), PSG can improve the coronal alignment of the TKA and decrease the operative time.

Materials and methods: Thirty-three lower limbs (from femoral head to foot) have been taken from seventeen cadavers. A pre operative CT scan of each lower limb has been realized in order to measure: Hip-Knee-Ankle angle (HKA), mechanical femoral angle (MFA) and mechanical tibial angle (MTA), and to plan the TKA for shaping the PSG. 17 TKAs have been implanted with PSG, 16 with SI. 54% (18/33) knees presented osteoarthritis at least on one of the three compartments. Post operatively, a further CT scan has been used to make the measure to compare the two groups. Per operatively, operative time and positioning of PSG have been reported.

Results: Pre operatively, 66,7% (22/33) of the lower limbs were in varus, 27,3% (9/33) were in valgus and 6% (2/33) were in neutral alignment, there was no significant difference between the groups. Post operatively: the overall mechanical alignment was between 177° and 183° for 81,25% (13/16) in SI group, and 76,47% (13/17) in PSG group. The mean HKA in SI was 179,1° +/- 2,45°, and 178° +/- 2,18° in PSG group, there was no significant difference between the group (p-Value: 0,17). Only the operative time was significantly lower in PSG group with a median of 43 minutes [35-47] relative to the SI group with a median of 50 minutes [43-62,5] (p-Value: 0,041).

Discussion: In our cadaveric study, PSG for TKA did not improve the coronal mechanical alignment of the lower limb compared with SI procedure. Indeed, we obtained post operatively a mean HKA angle closer to 180° in SI group than in PSG group, and the percentage of outliers from 180° +/- 3° was lower in SI group with 18,75% versus 23,5% in PSG group.
On the contrary, the operative time was significantly reduced in PSG group compared to standard instrumentation group. This result is corroborated by many authors. Some of them add that this diminution can lead to a reduction of cost effectiveness, despite of the price of this new technology.
The emergence of this technique, raise to a new concept of alignment of TKA, focused on kinematic alignment of the lower limb.
But further study is necessary to compare custom cutting guides with traditional instruments

and computer navigation with regards to long term implant survival and functional outcome, regardless the type of lower limb alignment.

Conclusion: in our study, PSG did not demonstrate a superiority regarding the coronal mechanical alignment comparing with SI in TKA. But the use of PSG process can reduce the operative time.

VU ET PERMIS D'IMPRIMER
Grenoble, le 22 août 2013

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Annex 1: Surgical technique

Set up:

The lower limb was placed on hand made support, designed especially in order to flex and bend the knee in all degrees of freedom.

Figure 1: set up

Surgical approach:

- When possible a midline knee incision was performed, from the distal part of the anterior tubercule of the tibia to 5 cm proximally from the patella. Some of the cadaveric knees had already been used during practical work performed by medical students and some of them had already a surgical approach. When it was the case, the same incision was chosen.

- Medial parapatellar arthrotomy: the incision followed the medial part of the tibial tubercule, up medially to the femoro-patellar ligament, and turned to the mid vastus at the proximal part of the patella. The medial collateral ligament was elevated from the tibia sufficient to gain sufficient access to the knee joint.

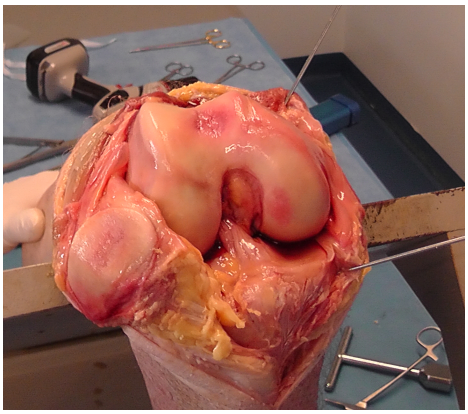

Figure 2: surgical approach

- Lateral everting of the patella.
- The cruciate ligaments, lateral and medial menisci were then removed.

Plumb Line measures:

- In order to check per operatively the axis of the lower limb, a plumb line test have been made at the beginning of the surgery process to check the correlation between the angles measured from the CT scan (especially HKA angle measure) and the distance between the plumb line and the landmarks.
  These measures were made before and after the knee replacement.

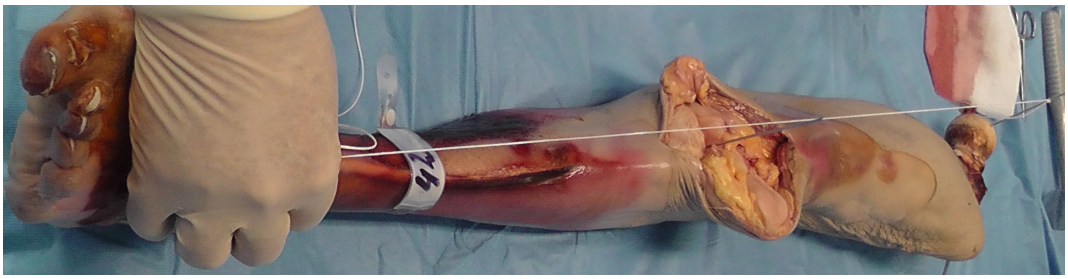

Figure 3: Plumb line measures

- Plumb line: from the hip center (obtained by placing a vernier caliper in two orthogonal plans and introducing a K-wire in the middle of both axes) to the ankle center (obtained by choosing the middle of the hook between the medial and lateral malleoli).

- In order to have a referent alignment, the distance (in millimeters) between the plumb line and corresponding anatomical landmarks was measured pre and post-operatively. The corresponding landmarks chosen were the internal edge of the anterior tibial tubercule, and the knee centre (middle of tibial spines or middle of tibial component). When the plumb line went medially from these anatomical landmarks the measure values was considered positive (negative if lateral).

Standard Instrumentation:

- firstly the proximal tibial cut was performed, using a intra medullary system, consisting mainly of a conventional cutting block with a posterior slope of 2°, and a probe placed on the less worm tibial plateau giving the cut height at 12 mm. The block was fixed with three pins. The proximal tibial cut was performed in caring for the insertions of the anterior and posterior cruciate ligaments.

- Secondary, the distal femoral cut was performed using also an intra-medullary system adjusted with the HKS (Hip-Knee-Summit) angle.

PSGs process:

- First the tibial PSG was placed after removing soft tissues in contact with fitting areas of the PSG. The tibial cut was done. The same process was done for the femoral cut.

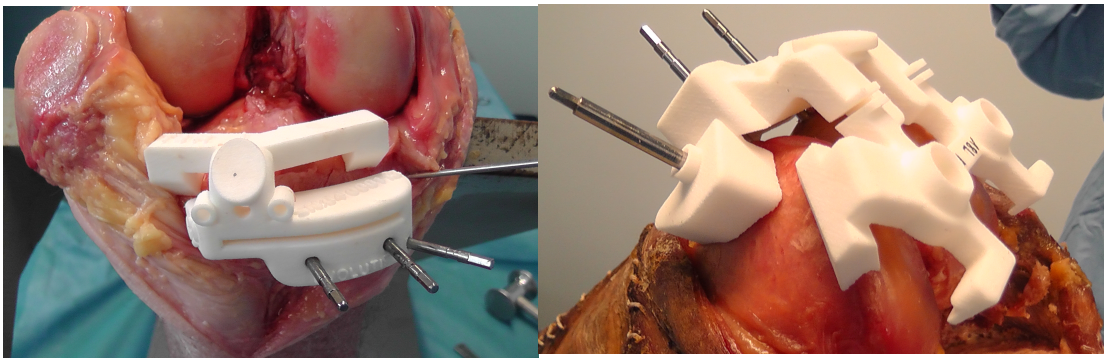

Figure 4: positionning of PSGs

- After tibial proximal cut and femoral distal cut, an long extra medullary spindle, fixed on template for PSG or on control guide, were involved to control the normal mechanical alignment of the components by matching the ankle's center and hip's center.

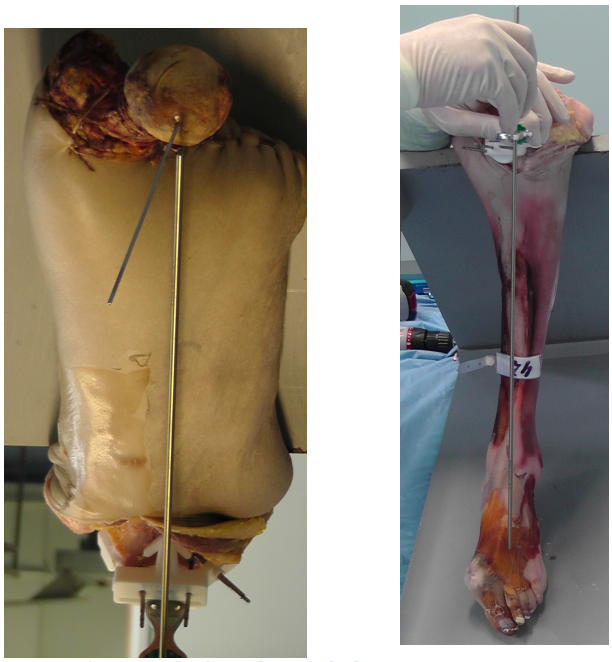

Figure 5: control of mechanical alignment

- Full extension was checked with a spacer equal to the height of definitive TKA.

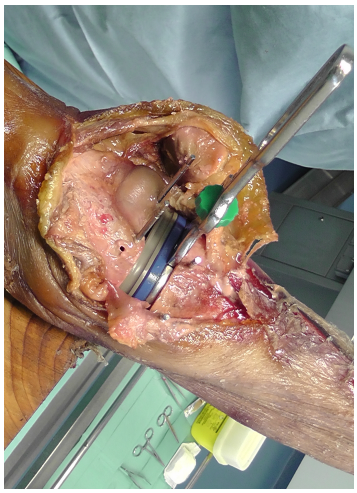

Figure 6: extension spacer

Components and ligaments balancing:

- Before tacking of the block cut, the ligament balance in flexion was checked and adjusted if necessary, the rotational alignment of the femoral was adjusted in order to have a flexion gap equal to the extension gap.

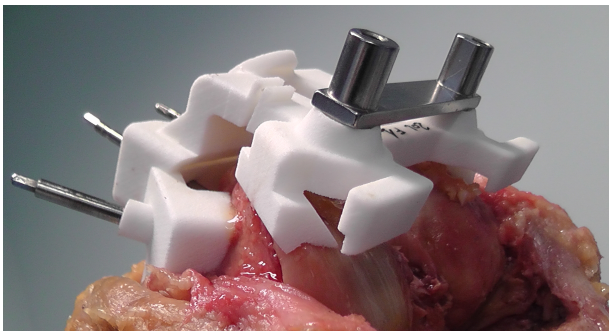

Figure 7: rotational alignment

- After the selection of internal, external or neutral rotation, the 4 in 1 cutting block was fastened on distal cut. Anterior and posterior cuts and chamfers were then performed.

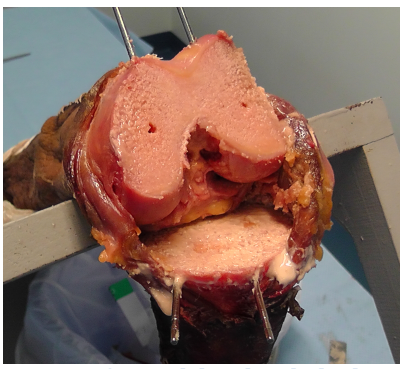

Figure 8: femoral distal and tibial proximal cuts

- The trail components were implemented according to components size planned preoperatively when using PSGs, or chosen regarding the tibial and femoral osteotomies sizes with standard instrumentation.

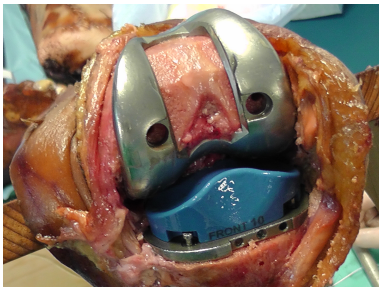

Figure 9: trail components

- The ligament imbalance was controlled in flexion and extension, and reported as tight, lax or normal. If one compartment was too tight a ligament release was performed as a pie-crusting. If both compartments were lax in flexion and in extension a higher polyethylene insert was used.

- Plumb line measurements were done again as a final control.

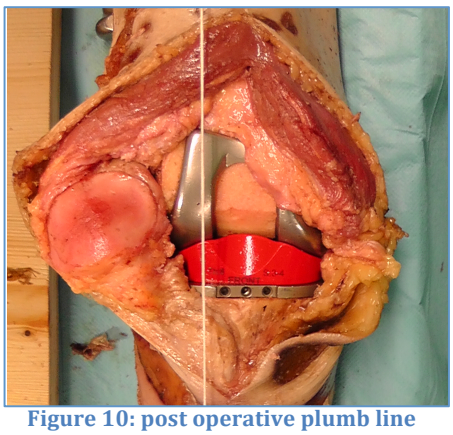

Figure 10: post operative plumb line measures

ANNEX 2: Tables of review

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean Coronal Mechanical alignment	Outliers	Mean Operative time (min)
Howell et al.(33)	MRI	OtisMed System	No	48	No	Mechanical	1.4° varus +/- 2.8°	NE	52 +/- 8 Touniquet
Klatt et al.(17)	MRI	OtisMed system	No	4	Yes	Mechanical	5° valgus to 7,5° varus	75%	NE
Lombardi et al.(10)	MRI	NC	No	54	No	Mechanical	4° to 8° valgus	NE	77
Gan et al.(39)	CT scan	NC	No	30	No	Mechanical	NC	0%	50
Bali et al.(40)	MRI	Visionnaire	No	32	No	Mechanical	179,9° +/- 2°	9,40%	67,8
Conteduca et al.(41)	MRI	Visionnaire	No	12	Yes	Mechanical	Tibial: 1,2 +/- 1,5, femoral: 1,2 +/- 0,6	Tibial : 16,7%, femoral : 8,3% (90°+/-2°)	NE
Delport et al.(42)	MRI	Signature	No	5	No	Mechanical	MFA 89,2°, MTA 89,4°	NE	65,6
Daniilidis et al.(43)	MRI	Visionnaire	No	100	No	Mechanical	178,5° +/- 1,7°	11%	52,5
Howell et al.(36)	MRI	OtisMed system	No	214	No	Mechanical	- 0.9° +/- 2.7°	27%	NE
Kerens et al.(38)*	CT Scan	Signature	No	10	No	Mechanical	2° (varus)+/- 1,7°	20%	83
Lustig et al.(44)	MRI	Visionnaire	No	60	Yes	Mechanical	179,8°	20,7%	NE

Table 1 : Review of non comparative studies. NE : Non Evaluated, NC : Non Communicated. * revision of Unicompartimental Knee arthroplasty to TKA

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean coronal Mechanical alignment	Outliers	Mean Operative time (min)
Hafez et al.(28)	CT scan	NC	Yes,SI	39 PSG/ 6 SI	No	Mechanical	Mean errors : Femoral: 1,02° Tibial: 1.06°	NE	9 PSG/ 15 SI (bone cutting)
Spencer et al.(34)	MRI	OtisMed system	Yes,SI	21 PSG/ 30 SI	No	Kinematic	1,2° varus +/-2,4°, NSD	9,52%	Tourniquet time: PSG 80+/-17, SI : 93 +/-12
Barrack et al.(45)	MRI	NC	Yes,SI	100 PSG/ 100 SI	No	Mechanical	PSG: 1,7° valgus+/- 2,5° SI:0,5° valgus+/- 2,3° SD	PSG: 31% SI: 23%	11 min lower in PSG
Boonen et al.(22)	MRI	Signature	Yes,SI	40 PSG/ 40 SI	No	Mechanical	PSG: 181° +/-4°, SI:179° +/-3°, SD	PSG:28,95%, SI :45,71%, NSD	PSG: 51, SI 61,SD
Conteduca et al.(46)	MRI	Visionnaire	Yes, EM tibial SI	12 (1st :EM, 2nd :PSG)	Yes	Mechanical	EM : 0,7° +/- 0,39° ; PSG : 1,29° +/-1,55°	PSG: 16,7% EM SI: 0% (90°+/-2°) NSD	NE
Dossett et al.(35)	MRI	NC	Yes, SI	41 PSG (k)/ 41 SI (m)	No	Mechanical	PSG 0,3° (varus)+/- 2,8° SI : 0°+/- 2,2°,NSD	NE	PSG : 106+/-20, SI : 127+/-24 SD
Ng et al.(16)	MRI	Signature	Yes,SI	569 PSG/ 155 SI	No	Mechanical	PSG: 180,6°, SI: 181.1°	14,4% PSG, 27,7% SI	NE
Noble et al.(15)	MRI	Visionnaire	Yes, SI	15 PSG/ 14 SI	No	Mechanical	PSG: 1.7°, SI: 2.8° SD	NE	PSG: 121.4 SI: 128.1 SD

Table 2 : Review of comparactive studies, NE : Non Evaluated, NC : Non Communicated, SD : Statistical Difference, NSD : Non Statistical Difference, EM : extramedullary .

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean coronal Mechanical alignment	Outliers	Mean Operative time (min)
Nunley et al.(18)	MRI	OtisMed system 1, Signature 2	Yes, 2 PSG gps and 1 SI gp	50 PSG1/ 50 PSG2 /50 SI	No	Mechanical	PSG1 : -2,76° PSG2 : -0, 65° SI : 0,08°	44% PSG1 18% PSG2 16% SI	NE
Yaffe et al.(47)	MRI	PSI system	Yes,CAS	111 PSG/30 CAS	Yes for CAS gp	Mechanical	PSG : 0,77° var. (5,5° val-5,8° var.)	17%	NE
Chareanc holvanich et al (21)	MRI	PSI system	Yes,SI	40PSG/ 40SI	No	Mechanical	PSG : 179,7°, SI :179,7°,NSD	PSG : 2,5%, SI :7,5% NSD	PSG : 62,9, SI : 68, SD
Nam et al.(48)	MRI	Signature	Yes,CAS	41 PSG/ 41 SI	Yes for CAS gp	Mechanical	PSG : 0,8 +/-2,9 CAS : 0,8 +/- 1,9	PSG : 29,30% CAS : 7,3%, SD	NE
Victor et al.(19)	MRI CT Scan	Signature 1, TruMatch 2, Visionnaire 3, PSI system 4	Yes, SI	61 PSG/ 64 SI	Yes	Mechanical	1 : 0,3° varus +/-1,4 2 : 0,9° varus+/- 2,3 3 : 0,5 varus+/- 3,4 4 : 0° +/- 1,8 SI : 0,9° varus+/-1,8	1 : 6% 2 : 25% 3 : 45% 4 : 19% SI : 28,1%	NE
Vundelinckx et al.(20)	MRI	Visionnaire	Yes, SI	31 PSG / 31 SI	No	Mechanical	PSG : 3°+/- 2,56 SI : 2,7°+/- 2,39,NSD	NE	NE
Our study	CT Scan	NC	Yes,SI	17PSG/ 16SI	No	Mechanical	PSG : 178°+/-2,18° SI : 179,1°+/-2,45°	PSG : 23,5% SI : 18,75%	PSG 43 SI 50, SD

Table 3 : Review of comparative studies. , gp : NE : Non Evaluated, NC : Non Communicated, SD : Statistical Difference, NSD : Non Statistical Difference, EM : extramedullary

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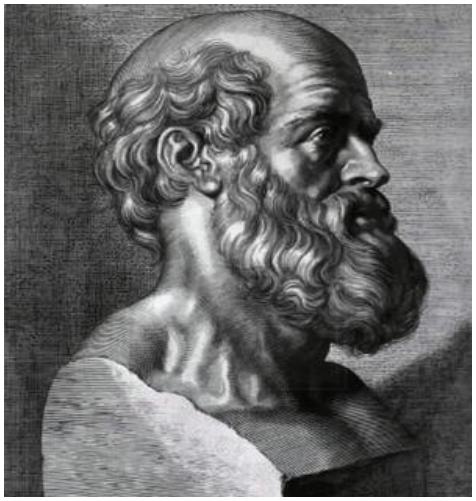

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de mes chers condisciples
et devant l'effigie d'Hippocrate,
Je promets et je jure d'être fidèle aux lois de l'honneur et de la probité dans
l'exercice de la médecine.
Je donnerai mes soins gratuitement a
l'indigent et n'exigerai jamais un salaire
au dessus de mon travail.
Je ne participerai a aucun partage clandestin d'honoraires.
Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y passe; ma langue taira les secrets qui me seront confies et mon etat ne servira
pas a corrompre les mœurs, ni a favoriser le crime.
Je ne permettrai pas que des considérations de religion, de nation, de race, de
parti ou de classe sociale viennent s'interposer entre mon devoir et mon patient.
Je garderai le respect absolu de la vie humaine.
Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.
Respectueux et reconnaissant envers mes Maîtres, je rendrai a leurs enfants l'instruction que j'ai reçue de leurs pères.
Que les hommes m'accordent leur estime si je suis fidèle a mes promesses.
Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.